DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

g3321d

VIA FEDERAL EXPRESS

Ref: Customs Entry No. EJ7-0027236-5/001
Product: Whole Pompano Fish (1000 lbs.)

WARNING LETTER

FLA-02-48

June 6, 2002

Jose Gomez, Owner
Tip Top Trading
910 N.W. 128th Court
Miami, Florida 33182

Dear Mr. Gomez:

The Food and Drug Administration (FDA), on May 10, 2002, attempted to examine a shipment of whole pompano fish in accordance with our Notice of FDA Action, dated May 8, 2002. The shipment was offered for entry into the United States by your firm on May 8, 2002, under the above referenced entry number.

On May 10, 2002, the FDA inspector noted that the shipment was unavailable for FDA examination. The product had been distributed prior to the FDA examination. Since your firm voluntarily decided to redeliver the shipment, FDA conducted a second examination of the lot at Guanabo Seafood, Miami, Florida. As per your request, on May 17, 2002, the FDA investigator conducted another examination of the product redelivered. FDA examination revealed that you were not successful in redelivering 1000 lbs. of pompano fish from this entry. This is in violation of Title 21, Code of Federal Regulations, Section 1.90, which requires the importer to hold an entry intact pending receipt of a "May Proceed Notice" or "Notice of Release" from FDA. We have requested the U. S. Customs Service (Customs) to order redelivery of 1000 lbs. of the whole pompano fish referenced above.

Failure to promptly correct this situation and prevent future premature distribution of imported product may result in U. S. Customs requiring that future shipments be held in secured storage, such as in a bonded warehouse. You would also be responsible for all costs incurred in obtaining secured storage.

We request a response in writing within fifteen (15) working days of receipt of this letter outlining the specific steps you have taken to correct the violation, including an explanation of each step being taken to prevent recurrence. In the event that the product is still available for examination, you should inform Customs and FDA, if and when redelivery is accomplished.

Your written reply should be addressed to the Food and Drug Administration, Attention: Paul R. Bagdikian, Compliance Officer, P. O. Box 59-2256, Miami, Florida 33159-2256.

Sincerely,

Martin E. Karl /for
Emma R. Singleton
Director, Florida District

cc: Thomas Winkowski
Port Director
U. S. Customs Service
P. O. Box 02-580
Miami, Florida 33102-5280